Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11516 Filed 5–8–96; 8:45 am]

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21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Medetomidine Hydrochloride Injection; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Orion Corp. ORION–FARMOS. The NADA provides for the use of medetomidine hydrochloride injection in dogs for its sedative and analgesic properties. The regulations are also amended to reflect a change of sponsor name.

EFFECTIVE DATE: May 9, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Orion Corp. ORION–FARMOS, (formerly Orion Corp. FARMOS), P.O. Box 425, SF–20101 Turku, Finland, filed NADA 140–999, which provides for intravenous or intramuscular use of Domitor® (medetomidine hydrochloride) injection as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The drug product is available by prescription. The application is approved as of March 19, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1335 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Additionally, the firm has informed FDA that it has changed its corporate name from Orion Corp. FARMOS to Orion Corp. ORION–FARMOS. Accordingly, the agency is also amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 19, 1996, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and by adding in its place ''Orion Corp. ORION–FARMOS'', and in the table in paragraph (c)(2) in the entry for ''052483'' by removing the sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and adding in its place ''Orion Corp. ORION–FARMOS''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

4. New § 522.1335 is added to read as follows:

§ 522.1335 Medetomidine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use.* As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations.* Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severly debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–11511 Filed 5–8–96; 8:45 am]

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21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Halofuginone Hydrobromide, Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration, HHS.